FEB 1 0 2012

SHENZHEN KINGYIELD TECHNOLOGY CO., LTD.
BP210 Wrist Blood Pressure Monitor

Annex 04

510(k) Summary

(as required by 21 CFR 807.92)

1. Submitter's Identification

Submitter's Name:	Shenzhen Kingyield Technology Co.,Ltd.
Address:	Section C1 C2, Fuhai Industrial Zone, Fuhai Road, Fuyong Town, Baoan District, Shenzhen, PR China
Phone:	+86-755-27326734
Fax:	+86-755-27331856
E-mail:	kingyield@kingyield.com
Contact person:	Mr. Dacheng Gong, General Manager
Date of Summary:	Jan, 10,2012

2. Product Classification

Trade Name:	BP210 Wrist Blood Pressure Monitor
Common Name:	Wrist Blood Pressure Monitor
Classification Name:	System, Measurement, Blood Pressure, Non-invasive
Class:	II
Regulation number:	870.1130
Product code:	DXN
Panel:	Cardiovascular

3. Identification of the legally marketed device

510(k) number:	083043
Trade Name:	BP201 Wrist Blood Pressure Monitor
Product Code:	DXN

4. Device Description:

BP210 Wrist Blood Pressure Monitor is designed to measure systolic and diastolic blood pressure, pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method is a well - known technique in the market called the "oscillometric method".

The device stores automatically 180 (2*90) sets of measurement values with the measuring date and time. You can read the stored data conveniently by pressing the memory button. If any irregular heartbeat is detected, the symbol IHB will be displayed on the LCD. Moreover, it has the function of averaging the last three measurement values. The memory data can be transferred to the PC by connecting

the device with the PC via USB cable.

5. Indications for Use:

BP210 Wrist Blood Pressure Monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method.

The device is intended for using in only adult population, not applied to the other populations such as neonatal baby.

It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

The cuff circumference is limited to 13.5cm – 21.5cm.

6. Summary of Technological Characteristics Compared to the Predicate Device:

The modified device BP210 and the predicate device BP201 use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Wrist cuff is inflated with the constant speed automatically, and the inflation pressures are transferred via tubing to one sensor.

The major differences between the two models are the additional features such as PC link function, blood pressure classification and bigger memory size.

Predicate Device:

Cleared Device Model: BP201, k083043 which is designed and manufactured by the same company and facility as the BP210 Wrist Blood Pressure Monitor

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Testing information demonstrating safety and effectiveness of BP210 Wrist Digital Blood Pressure Monitor in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted:

a. Reliability Test - Storage test according to ANSI/AAMI SP10:2002/A1:2003/4.2.1 and EN 1060-1:1996/7.1.2.1
b. Reliability Test - Operating test according to ANSI/AAMI SP10:2002/A1:2003/4.2.2 and EN 1060-1:1996/7.1. 1
c. Reliability Test - Vibration test according to ANSI/AAMI SP10:2002/A1:2003/4.2.3 and EN 1060-1:1996/7.2. 2

d. Reliability Test - Drop test according to ANSI/AAMI SP10:2002/A1:2003/4.5.4.1B and EN 1060-3:1996/7.4. 1
e. Reliability Test - Life test according to ANSI/AAMI SP10:2002/A1:2003/4.2.4.2 and EN 1060-3:1997/7.6
f. EMC Test according to IEC 60601-1-2:2007 (Third edition)
g. Safety Test according to IEC 60601-1:1988+A1:1991+A2:1995
h. Performance Test-according to EN1060-1:1995/A1:2002 and EN 1060-3:1997/A1:2005
i. Biocompatibility Test Report according to ISO 10993-5:2009 and ISO 10993-10:2002/Amd.1:2006

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that BP210Wrist Blood Pressure Monitor tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

ANSI/AAMI SP10: 2002 "National Standard for Manual, Electronic or Automated Sphygmomanometers" testing was performed. All relevant sections were addressed and testing conducted. The BP210 met all relevant requirements of this standard, as applicable to our modified device. The BP210 is, from a technical point of view, identical to the predicate device, Model BP201. Moreover, the measurement algorithm and its program codes of the BP210 remain unchanged. The fundamental scientific technology of the modified BP210 device is the same as the predicate BP201 device. Therefore the performance of the BP210 in terms of blood pressure measurement would be identical with performance of the predicate BP201 device. Repeat clinical testing in accordance with the standard ANSI/AAMI SP10 for the subject BP210 device is therefore not necessary as clinical testing results were not affected by the changes to the subject modified device.

9. Conclusions:

We have demonstrated that there are no significant differences between BP210 Wrist Blood Pressure Monitor and the predicate devices, Model BP201, in terms of safety and effectiveness based on electrical, mechanical and environmental test results per the FDA DCRND November 1993

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 10 2012

Shenzhen KingYield Technology Co., Ltd
c/o Mr. Michael S. Ogunleye
TUV Rheinland of North America, Inc.
12 Commerce Road
Newtown, CT 06470

Re: K112042
Trade/Device Name: KingYield Wrist Blood Pressure Monitor, Model 210
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: January 13, 2012
Received: January 24, 2012

Dear Mr. Ogunleye:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Annex 03

Indications for Use Statement

510(k) number: K112042

Device Name: BP210 Wrist Blood Pressure Monitor

Indications for Use:

BP210 Wrist Blood Pressure Monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method.

The device is intended for using in only adult population, not applied to the other populations such as neonatal baby.

It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

The cuff circumference is limited to 13.5cm – 21.5cm.

Prescription Use _____ AND/OR Over-The-Counter Use ✓ (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112042

03-1